In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

JIM BYNUM,	*	
	*	No. 18-874V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	
	*	Filed: April 11, 2024
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Milton Clay Ragsdale, IV and Allison Riley, Ragsdale, LLC, Birmingham, AL, for Petitioner;
Madelyn Weeks, United States Dep't of Justice, Washington, D.C., for Respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

At age 74, Jim Bynum, who had a complex medical history, received a pneumococcal vaccine. His health worsened. He claims the vaccination harmed him and asserts essentially two causes of action. First, the pneumococcal vaccine significantly aggravated a previously undiagnosed Sjögren's syndrome. Second, the pneumococcal vaccine caused him to suffer lumbosacral radiculoplexus neuropathy, another condition with which a treating doctor did not diagnose him

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

during treatment. The Secretary challenges Mr. Bynum's entitlement to compensation on several grounds.

To assist them, the parties retained experts. Mr. Bynum primarily relies upon the opinions of David Younger, a neurologist. Mr. Bynum also advances the opinion of G. Clement Dobbins, who earned a Ph.D. in neurobiology, but is not a medical doctor. Finally, Mr. Bynum presents letters from a doctor who treated him before and after the pneumococcal vaccination, Joshua Reams. The Secretary is relying upon opinions from two people. They are Brian Callaghan, a neurologist, and Christopher Mecoli, a rheumatologist.

When the written evidence was complete, the parties advocated through briefs. Neither party requested a hearing.

Mr. Bynum is not entitled to compensation. As explained below, he has not established that he suffers from the conditions for which he seeks compensation.

I. Qualifications of People Presenting Opinions

As a preliminary point, the credentials of the people offering opinions are set forth.

A. Mr. Bynum's Group[2]

David Younger. David Younger earned a medical degree from Columbia University in 1981. More recently, he has earned additional degrees in 2014 (a master's in public health), in 2016 (a Master of Science for epidemiology) and in 2020 (a Ph.D. in health policy management). Exhibit 74 (curriculum vitae) at 1.

Dr. Younger completed a residency in neurology in 1984. He also completed various fellowships in 1986, 1987, and 1988. He became board-certified in neurology and psychiatry in 1992. Id.

He has written more than 50 articles appearing in peer-reviewed journals. He has also written books and book chapters. Id. at 5-20.

From February 2017 to February 2020, his license to practice medicine in New York was suspended and the suspension was stayed. Exhibit 73. This suspension followed Dr. Younger's pleading guilty to one count of tax fraud.

[2] Mr. Bynum did not submit any information about Dr. Reams's qualifications.

When Dr. Younger submitted his first report dated October 22, 2022, he stated that he had treated "10 patients with presumed primary microscopic vasculitis and Sjogren's syndrome over the past five years." Exhibit 30 at 2.

G. Clement Dobbins. G. Clement Dobbins earned a Ph.D. in neurobiology from the University of Alabama. Exhibit 71 (curriculum vitae) at 1. He has been a postdoctoral fellow, focusing on virology, gene therapy, oncology, and bioinformatics. Id. His curriculum vitae lists approximately ten articles he has written for peer-reviewed journals. Id. He received grant funding to track "how antigens expressed by SARS-CoV-2 and cytomegalovirus change within and between patients over time and how these changes may trigger an altered immune response in patients including those with immune dysfunction." Exhibit 57 (report) at 1.

Dr. Dobbins was asked to discuss "how the pneumococcal vaccine given to Mr. Bynum could lead to his symptoms." Id. Dr. Dobbins did not offer any opinions regarding diagnosis.

B. The Secretary's Group

Brian Callaghan. Brian Callaghan earned a medical degree from the University of Pennsylvania in 2004. Exhibit I (curriculum vitae) at 1. In the following five years, Dr. Callaghan completed an internship, a residency in neurology, and a fellowship in neuromuscular medicine. He is board-certified in psychiatry and neurology as well as electrodiagnostic medicine. Id. His research interests include the "evaluation of peripheral neuropathy" and "efficient diagnostic testing in common neurologic disorders." Id. at 2.

He has written more than 100 articles appearing in peer-reviewed journals. Id. at 14-20. When Dr. Callaghan prepared his first report, dated July 12, 2021, he represented that he treats "approximately 10 patients with vasculitic neuropathy each year." Exhibit A at 1.

Christopher Mecoli. Christopher Mecoli graduated from Rutgers University with a medical degree in 2011. Exhibit D (curriculum vitae) at 1. In the next few years, Dr. Mecoli completed an internship in medicine, a residency in medicine, and a fellowship in rheumatology. Id. Dr. Mecoli is board-certified in internal medicine (2014) and rheumatology (2017). Id. at 6.

He has written more than 25 articles, appearing in peer-reviewed journals. Id. at 1-4. His research focuses "on the study of both idiopathic inflammatory myopathies and systemic sclerosis." Id. at 7.

In his first report, Dr. Mecoli stated that he "regularly evaluate[s] and treat[s] patients with Sjogren's syndrome and inflammatory arthritis, as well as mimics of rheumatic disease." Exhibit C at 1. Dr. Mecoli did not estimate the number of patients he has treated.

II. Conditions Allegedly Affecting Mr. Bynum

A. Sjögren's Syndrome

A basic definition of Sjögren's syndrome is that it is a "chronic autoimmune, rheumatic disorder most commonly characterized by dryness of eyes and mouth due to lymphocytic infiltration of the lacrimal and salivary glandular tissues." Exhibit 42 (Fox) at 1.[3] According to this medical textbook, "we still really do not understand the underlying cause of SS [Sjögren's syndrome]. Its epidemiologic pattern suggests that both genetic and nongenetic factors (e.g. environmental or epigenetic modifications) play a role." Id. at 8.

Diagnosing Sjögren's syndrome can be challenging as its presentation can be "remarkably heterogeneous." Exhibit C (Dr. Mecoli's report) at 5; accord Exhibit 43 (Vivino) at 21.[4] Diagnosis should involve "a comprehensive, systematic, multidisciplinary evaluation." Exhibit 42 (Fox) at 11. Because "no universally accepted diagnostic criteria exist for Sjogren's syndrome, many clinicians utilize classification criteria to aid in guiding the diagnostic process." Exhibit C (Dr. Mecoli's report) at 5.

Researchers have proposed various sets of diagnostic criteria, which have had variable sensitivities and specificities. The currently predominant set of criteria blend the best parts of previous criteria developed by the American College of Rheumatology and the European League Against Rheumatism. Exhibit 43 (Vivino) at 27. A simplified summary of the criteria is:

1. Anti-SSA positivity **or** RF + ANA (≥ 1:320)

2. Positive lip biopsy [details omitted]

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[3] Robert Fox et al., "Sjögren's syndrome: past, present, and future" *in* Sjögren's Syndrome: A Clinical Handbook (Frederick B. Vivino, 2020), filed as Exhibit 42.

[4] Frederick Vivino, "Diagnosis and evaluation of Sjögren's syndrome," *in* Sjögren's Syndrome: A Clinical Handbook (Frederick B. Vivino, 2020), filed as Exhibit 43.

3. Objective evidence of dry eyes [details omitted]

4. Objective evidence of salivary gland involvement [details omitted].

Id. at 29 (table 2.7); see also Exhibit C at 5 (Dr. Mecoli discussing the diagnostic criteria found in table 2.7). To qualify, a person must have at least three of these criteria and no other explanation for the disease. Exhibit 43 (Vivino) at 29.

The first criterion "Anti-SSA positivity or RF + ANA" refers to different types of antibodies. "RF" means rheumatoid factor. "ANA" means "anti-nuclear antibodies." "Anti-SSA" refers to Sjogren's syndrome-associated antigen and is sometimes known as "anti Ro" because the person in whom the antibodies were first detected had the initials "Ro". Exhibit 42 (Fox) at 6; see also Dorland's at 99. Another type of antibody that sometimes appears in the literature is called "Anti-SSB" and is also known as "anti Lo." Id.

"[A]ntibodies to SS-A may be present in 'asymptomatic' individuals many years before any clinically detectable SS." Exhibit 42 (Fox) at 6-7. "Furthermore, . . . the finding of antibodies to SS-A in clinical screening does not always equate to a diagnosis of SS." Id. at 7.

"In about 80% of SS patients the disease begins with some form of the sicca syndrome (from the Latin *siccus* meaning dry or thirsty) characterized by the gradual onset of dryness of the eyes, mouth, and other body parts that develops over months to years." Exhibit 43 (Vinvio) at 22. "In the remaining 20% of cases, an internal organ or extraglandular manifestation will predominate and sicca symptoms may be minimal or nil at the time of initial evaluation. This atypical presentation is particularly common among SS patients who present with neurologic manifestations (Chapters 9, 10) of the disease." Id.

Chapter 9 of this medical textbook, in turn, was written by Dr. Younger, who is opining on behalf of Mr. Bynum. In this context, Dr. Younger wrote: "Neuropathies in SS can be the presenting manifestations of the disease or occur later in the course." Exhibit 46 (Younger) at 153.[5] In the remainder of this chapter, Dr. Younger describes various disorders of the peripheral nervous system

[5] David Younger, "Sjögren's syndrome: peripheral and autonomic nervous system involvement," *in* Sjögren's Syndrome: A Clinical Handbook (Frederick B. Vivino, 2020), filed as Exhibit 46.

and the autonomic nervous system associated with Sjögren's syndrome. However, none of the various conditions are highlighted.

B. Vasculitic Peripheral Neuropathy[6]

"Vasculitis" means "inflammation of a blood or lymph vessel." Dorland's at 1996; accord Rocha v. Sec'y of Health & Hum. Servs., No. 16-241V, 2024 WL 752787 (Fed. Cl. Spec. Mstr. Feb. 1, 2024). Diseases caused by inflammation of blood vessels are known as "vasculitides." Exhibit 31 (Hadden) at 1567.[7] "The vasculitides may be triggered by immune reaction to certain antigens, including infectious agents, possibly explaining the aetiology of post-immunisation vasculitis. Due to the relative lack of collateral blood flow and high metabolic demand, nerves are particularly susceptible to vasculitic injury." Id. at 1567-68.

"Peripheral neuropathy is very common in the general population. The clinical features which best distinguish [vasculitic peripheral neuropathy] from other more common peripheral neuropathies are multifocality in time ('stepwise') and space (multifocal or asymmetric pattern)." Exhibit 31 (Hadden) at 1573. "Clinically, vasculitic neuropathies are usually painful and asymmetric, with sensory, motor, and autonomic involvement." Id. at 1567.

As part of the Brighton Collaboration, a group of researchers attempted to establish diagnostic criteria for vasculitic peripheral neuropathy.[8] They ended up with sets of criteria, corresponding to definite (table 2), probable (table 3), and suggestive (table 4). Id. at 1571-72; see also Resp't's Br. at 43 (discussing three levels of confidence). "The Level 3 definition relies entirely on the typical clinical features of vasculitic neuropathy. . . . First, there should be evidence of abnormality of the peripheral nervous system . . . . Second, the clinical features of

[6] The parties' briefs regarding vasculitic peripheral neuropathy could have been clearer.

[7] Robert Hadden et al., "Vasculitic peripheral neuropathy: Case definition and guidelines for collection, analysis, and presentation of immunization safety data," 35 Vaccine 1567 (2017), filed as Exhibit 31. Dr. Younger edited a book called "The Vasculitides." See Exhibit 37.

[8] The Brighton Collaboration is an "international group of vaccine safety reports [and] [o]ne of the Collaboration's roles is establishing standard case definitions for various illnesses and disorders that are temporally related to vaccinations, known as 'adverse events following immunization.'" Tompkins v. Sec'y of Health & Hum. Servs., No. 10-261V, 2013 WL 3498652 (Fed. Cl. Spec. Mstr. June 21, 2013), mot. for rev. denied, 117 Fed. Cl. 713 (2014).

the neuropathy should be those with the greatest positive predictive value for VPN relative to other neuropathies." Id. at 1572.

The term "vasculitic peripheral neuropathy" encompasses various subtypes. See Exhibit 31 (Hadden) at 1571. One subtype is known as lumbrosacral radiculoplexus neuropathy. Id.; see also Exhibit 37 (Younger) at 250. Lumbrosacral radiculoplexus neuropathy can be diabetic or nondiabetic in origin. Regardless, they usually involve "the distal and proximal limbs asymmetrically. They begin focally and unilaterally, but often become widespread and bilateral. These diseases affect lumbrosacral roots, lumbrosacral plesux, and lower limb peripheral nerves." Exhibit A-2 (Gwathmey) at 72.[9] Electrodiagnostic studies "characteristically show acute-to-subacute axonal loss of sensory and motor fibres, frequently in a patchy, multifocal distribution. Electrodiagnostic findings that are most supportive of a diagnosis of vasculitic neuropathy are those indicative of asymmetrical or non-length dependent patterns of axonal neuropathy." Id. at 73.

III. Events in Mr. Bynum's Life

Mr. Bynum's medical history is divided into two periods. The first period concerns his health before the allegedly casual vaccination. The second period concerns his health after the allegedly casual vaccination.

A. Before Vaccination

For Mr. Bynum's health before vaccination, the parties have different perspectives. Mr. Bynum recounts evidence regarding his pre-vaccination health in a single paragraph. Pet'r's Br. at 1. In contrast, the Secretary's summary runs approximately four pages. Resp't's Br. at 2-5.

Mr. Bynum was born in 1941. Exhibit 3 at 1. According to histories created in 2013, 2015, and 2018, Mr. Bynum developed rheumatoid arthritis in the 1960's and diabetes in the 1980's. Exhibit 5 at 78, Exhibit 21 at 6, Exhibit 23 at 28. Mr. Bynum agrees that he suffered from these problems, although in his view, they were "under control and not severe or disabling pre-vaccination." Pet'r's Br. at 1.

In January 2013, Mr. Bynum saw a rheumatologist, Aymen Kenawy, for the first time. Exhibit 23 at 28. Mr. Bynum reported a series of problems, including muscle aches, night sweats, dry eyes, and dry mouth. Id. at 30. The chief complaint was diffuse joint pain. Id. at 28. On physical examination, Dr. Kenawy

[9] Kelly Gwathmey et al., "Vasculitic neuropathies," 13 Lancet Neurol 67 (2014).

detected limited range of motion and tenderness. Id. at 31. Dr. Kenawy's examination of Mr. Bynum's eyes and mouth did not reveal any abnormalities. Id.

Dr. Kenawy's "working diagnoses include (but are not limited to) osteoarthritis, inflammatory arthritis and chronic widespread pain syndrome." Id. at 31. He ordered ultrasounds of various joints and prescribed Flexcin. Id.; see also Exhibit 39 (Dr. Younger's report) at 1.

In addition, Dr. Kenawy ordered an array of blood tests. Many tests returned an expected or normal result, such as a test for anti-nuclear antibodies. Exhibit 31 at 25-27; see also Exhibit C (Dr. Mecoli's report) at 2. One relevant positive test was a test for SS-A antibodies. This test returned a result of 1.0 and the expected result is to be lower than 1.0. Exhibit 31 at 44. Dr. Mecoli commented that "While this technically is above the upper limit of normal, it is not considered a robust, high-titer autoantibody level." Exhibit C at 6. Although Dr. Younger mentioned the positive SS-A result (Exhibit 39 at 2), Dr. Younger did not refer to this positive result as supporting Dr. Younger's diagnosis of Sjögren's syndrome.

A return visit with Dr. Kenawy occurred on March 6, 2013. Exhibit 23 at 23. A purpose was to review the labs and ultrasounds. Id. In this appointment, as in the January 10, 2013 appointment, Mr. Bynum reported muscle aches and joint pain. Id. at 25. However, on March 6, 2013, Mr. Bynum denied having dry eyes and denied having dry mouth. Id. Dr. Kenawy assessed Mr. Bynum as suffering from an unspecified inflammatory polyarthropathy and prescribed Enbrel. Id. at 28. Dr. Kenawy did not diagnose Mr. Bynum as suffering from Sjögren's syndrome.

After the March 6, 2013 appointment, Mr. Bynum returned for rheumatological care with Dr. Kenawy five additional times. Exhibit 23 at 4-22. He denied having dry eyes and dry mouth consistently.

The appointments with Dr. Kenawy overlapped with appointments with a primary care doctor, Sanders McKee. See Exhibit 10. However, these records do not affect whether Mr. Bynum is entitled to compensation. See Exhibit 39 (Dr. Younger's report) at 1-2 (omitting any discussion of records from Dr. McKee).

Mr. Bynum had his first appointment with a different primary care doctor, Dr. Reams, on June 5, 2014. Exhibit 5 at 3. Dr. Reams worked for Bay Medical Sacred Heart. The chief complaint was a cough.

Between June 5, 2014 and June 8, 2015, Mr. Bynum saw Dr. Reams for a variety of problems across 11 visits. Exhibit 5 at 3-57. There are no notations about Mr. Bynum complaining of dry eyes or dry mouth. None of Dr. Reams's records mention the positive SS-A test. Dr. Reams did not diagnose Mr. Bynum as suffering from Sjögren's syndrome.

On June 25, 2015, Mr. Bynum was riding his motorcycle without a helmet and fell off it. Exhibit 4 at 3-4 (record created on June 30, 2015). Mr. Bynum reported that he did not hit his head and that he did not lose consciousness. Id.

B. Vaccination and Thereafter

1. June through October 2015

Mr. Bynum received the allegedly causal pneumococcal vaccine on June 26, 2015. Exhibit 1 at 3. (Some medical records refer to this pneumococcal vaccine as "PCV 13," or by its brand name, Prevnar).[10]

Four days later, Mr. Bynum sought care from a different office of Bay Medical Sacred Heart, where a doctor other than Dr. Reams saw him. Mr. Bynum told Dr. Brian Shaheen about his motorcycle accident. In addition, Mr. Bynum stated that he had received pneumovax and "ever since then has not felt well." Exhibit 5 at 58. Specific problems included "dizziness for four days," "unstability," and "headaches." Id. Dr. Shaheen stated that his findings of generalized weakness and quavering voice were not specific. Id. at 62. He worried that Mr. Bynum might have "Guillain Barré syndrome, early encephalitis [or a] metabolic disorder" and sent him directly to the emergency room. Id.

Mr. Bynum did not go to the emergency room. Exhibit 5 at 64. According to a statement signed under penalty of perjury in 2018 by Mr. Bynum's then girlfriend, Mr. Bynum did not drive to the emergency room because of his "mental confusion and illness." Exhibit 18 (statement of Melinda Leslie) ¶ 6.

Ms. Leslie averred that over the next several weeks, Mr. Bynum "did not improve." Id. ¶ 7. He was weak, had no appetite, and was losing weight. He "was not mentally alert and at time barely responsive." Id. "The sudden deterioration in

[10] References to Mr. Bynum receiving a pneumovax vaccine are incorrect. The Vaccine Program does not compensate people for harm caused by the pneumovax vaccine. Byrd v. Sec'y of Health & Hum. Servs., 142 Fed. Cl. 79, 84 (2019), aff'd, 778 Fed. Appx. 924 (Fed. Cir. 2019).

[Mr. Bynum's] physical and mental health that started shortly after the vaccination was astonishing to [Ms. Leslie]." Id.

Some of Ms. Leslie's recollections match a report that Mr. Bynum provided to Dr. Reams on July 27, 2015, approximately one month after the vaccination. Mr. Bynum presented to Dr. Reams to discuss "side effects from Prevnar vaccine." Exhibit 5 at 64. Mr. Bynum informed Dr. Reams that he has been having night sweats, fatigued, and not eating much. Mr. Bynum also reported generalized weakness. He also said he is "somewhat better now." Id.

Dr. Reams assessed Mr. Bynum as having two conditions: fatigue and confusion. Under fatigue, Dr. Reams wrote: "This may all be a reaction to vaccine but we need to rule out other issues." Exhibit 5 at 67. Dr. Reams ordered a series of labs. Id. Whether Mr. Bynum was tested is not readily apparent.

Over the next week, Mr. Bynum visited an emergency room twice. On July 30, 2015, Mr. Bynum reported having a cough, chills, fever, and myalgias. Exhibit 6 at 5-6. The doctor diagnosed him with bronchitis and prescribed medications. On August 4, 2015, Mr. Bynum reported problems, including decreased responsiveness. Id. at 15-16. He was given Narcan and became more alert. The doctor stated that Mr. Bynum had taken too much of the medication that had been prescribed a few days earlier.

Mr. Bynum's next medical appointment was with Dr. Reams on August 27, 2015. Exhibit 5 at 69. Mr. Bynum complained about chronic fatigue, starting six weeks earlier. Mr. Bynum also reported joint pain. For the fatigue, Dr. Reams recommended adjusting a medication, gabapentin. For the joint pain, Dr. Reams gave a Kenalog shot. Id. at 71.

Although not documented in the August 27, 2015 record, it appears that Dr. Reams referred Mr. Bynum to a neurologist, whom he saw on August 31, 2015. Exhibit 7 at 23. Mr. Bynum told Dr. George Barrio that he:

> has been typically in a normal state of health until June after a Prevnar vaccination and some time before a viral infection, in which he started developing significant issues with dizziness, headache, slight altered mental status, dysphagia, tremor with difficulty with coordination that have all been slightly progressive since the onset.

Id. As part of Dr. Barrio's review of systems, Dr. Barrio noted Mr. Bynum reported "blurred vision, dry eyes, eye pain, difficulty swallowing and pain when swallowing." Id. at 24. On examination, Dr. Barrio detected a "slightly increased

tone." Id. at 25. A sensory examination revealed: "Length-dependent loss to pinprick, temperature, and vibration. Reflexes trace in uppers, absent in lowers." Id. Dr. Barrio's impression included neuropathy, among other problems. Dr. Barrio ordered three types of tests---an EEG, a MRI, and electromyography/nerve conduction studies. Id. at 25.

The first test, the EEG, was normal. Exhibit 7 at 22 (Sep. 10, 2015). The second test, a brain MRI, showed some abnormal focal areas. Id. at 20 (Sep. 24, 2015). However, Mr. Bynum has not suggested that the brain MRI contributes to the dispute over diagnosis. See Pet'r's Br.

The third set of tests, the EMG / NCS, are more consequential. See Pet'r's Br. at 5. One set of EMG / NCS tests were performed on Mr. Bynum's upper extremities. The results suggested "mild chronic multilevel cervical radiculopathy." Exhibit 7 at 15 (Oct. 1, 2015). The other set of EMG / NCS tests were performed on Mr. Bynum's lower extremities and were abnormal. The results were "highly suggestive of peripheral neuropathy. . . . The above electro diagnostic study also reveals evidence of moderate chronic multilevel lumbosacral radiculopathy on the right and left." Id. at 10 (Oct. 15, 2015).

When this testing was complete, Mr. Bynum returned to Dr. Barrio. He reported "there are no significant changes, but still is adamant regarding variety of the symptoms after his Prevnar immunization." Exhibit 7 at 5 (Oct. 23, 2015). The results of a neurologic examination were similar to the results on August 31, 2015. In Dr. Barrio's plan, he specifically wrote about various problems and tests, but not the lower extremity MRI. See id. at 7. Dr. Barrio anticipated that Mr. Bynum would return in four weeks. Id. However, it appears that Mr. Bynum next saw Dr. Barrio nearly two years later. See Exhibit 11 at 10 (report from Aug. 23, 2017).

2. November 2015 through 2016

Although Mr. Bynum stopped seeing Dr. Barrio, Mr. Bynum continued to see other doctors, primarily Dr. Reams, throughout the remainder of 2015 and 2016. There were approximately 10 visits. For details, see Resp't's Br. at 10-11. These records do not memorialize any complaints about dry mouth or dry eyes. See Exhibit 5 at 78-135. Similarly, Dr. Reams's notes do not suggest that Mr. Bynum suffered from Sjögren's syndrome. However, on December 4, 2015, Dr. Reams informed the Vaccine Adverse Event Reporting System that Mr. Bynum "received Prevnar 13 on 6/26/15. The next day or so he began having pain in joints all over his body, fatigue, weakness, irritability + hypersomnolence. He

continues to have these symptoms." Exhibit 28 at 1; accord Exhibit 5 at 90-92 (Dr. Reams's December 1, 2015 record stating that Mr. Bynum's symptoms of weakness, increased pain in his hips and legs, increased somnolence and loss of appetite "are best explained by an adverse [reaction] to Prevnar given on 6/26/15").

In his brief, Mr. Bynum points to a gastroenterologist's record from this time. Pet'r's Br. at 2. On November 16, 2015, Mr. Bynum saw Shilpa Reddy. Mr. Bynum reported difficulty with swallowing that began gradually. Exhibit 24 at 4. Dr. Reddy recommended an endoscopy to evaluate for esophageal structural abnormality. Id. at 6. Whether Mr. Bynum underwent an endoscopy is not clear.[11]

3. 2017 through 2022

In 2017, Mr. Bynum returned to Dr. McKee for the first time in approximately three years. Exhibit 38 at 4 (May 25, 2017). Dr. McKee investigated Mr. Bynum's report of a weight loss.

Later in 2017, as mentioned earlier, Mr. Bynum saw a neurologist, Dr. Barrio, for the first time in approximately two years. Exhibit 11 at 10 (Aug. 23, 2017). In the next appointment, Dr. Barrio recommended an EMG / NCS. Id. at 6.

The EMG / NCS took place on October 3, 2017. Exhibit 14 at 15. For Mr. Bynum's lower extremities, the EMG / NCS showed "a severe length-dependent peripheral neuropathy that appears to have more axonal greater than demyelinating features." Id. "Clinical correlation is strongly advised." Id.

In a follow-up appointment, Mr. Bynum saw Stephen Johnson, ARNP-FNP, on October 20, 2017. Id. at 9. In a review of systems, Mr. Bynum denied dry mouth. Id. at 10. Mr. Johnson planned "to do some extensive lab work for further evaluation. . . . He is going to see Dr. Barrio next visit." Id. at 11. However, the results of any additional testing were not provided. Mr. Bynum saw Dr. Barrio on November 11, 2017, and recommended a follow-up appointment in four weeks. Id. at 5. It appears that Mr. Bynum did not see Dr. Barrio again. See Resp't's Br. at 13.

In 2018 and 2019, Mr. Bynum sought care from Dr. McKee for a variety of problems. See Exhibit 13 and Exhibit 27. During these appointments, it appears that he did not report dry mouth or dry eyes. See Exhibit 13 at 27-36, passim;

[11] It appears that Mr. Bynum reported that he had "upper endoscopy;" however, it is unclear whether he actually underwent the procedure. See Exhibit 24 at 8.

Exhibit 27. Diagnoses included various medical conditions but not Sjögren's syndrome. In November 2019, Mr. Bynum had an appointment with Dr. Reams for the first time in approximately three years. Exhibit 76 at 57. Mr. Bynum complained about an upper respiratory infection. Id. Records from Dr. Reams continue through 2022. During these visits, it appears that Mr. Bynum did not report dry mouth or dry eyes nor is there any mention of Sjögren's syndrome. Exhibit 76, passim.

IV. Procedural History

Represented by Attorney M. Clay Ragsdale, Mr. Bynum started this litigation by filing his petition on June 20, 2018. He periodically filed medical records and other factual materials.

The Secretary reviewed this evidence and recommended that compensation be denied. Resp't's Rep., filed June 19, 2019. The Secretary asserted that Mr. Bynum's "allegation of a number of symptoms he purportedly experienced following his vaccination does not amount to a compensable, medically-recognized injury." Id. at 12. The Secretary argued: "Assuming, arguendo, that petitioner can show by preponderant evidence that he suffered from a compensable, medically-recognized injury and that he suffered the sequela of that injury for more than six months, he also must establish by preponderant evidence that the Prevnar 13 vaccine was the "legal cause" for his injury under the *Althen* test . . ." Id. The Secretary stated that Mr. Bynum did not file any expert reports in support of his petition. Id. at 13.

To facilitate the process of obtaining useful reports from experts, a set of instructions were proposed. Order, issued Oct. 31, 2019. After neither party interposed any objections, the draft instructions became final on November 22, 2019.

After receiving multiple enlargements of time, Mr. Bynum submitted a report from Dr. Younger on October 23, 2020. Exhibit 30. Dr. Younger proposed that Mr. Bynum suffered from "autoimmune lumbosacral radiculoplexus neuropathy due to microscopic vasculitis." Id. at 4. Dr. Younger did not suggest that Mr. Bynum was affected by Sjögren's syndrome. See id. Dr. Younger opined that the onset of the autoimmune lumbosacral radiculoplexus neuropathy was within 48 hours of the vaccination. Id. at 7. However, Dr. Younger did not cite the medical record corresponding to this proposed onset. To explain how the pneumococcal vaccine could cause autoimmune lumbosacral radiculoplexus

neuropathy, Dr. Younger referred to polyclonal B cells. Id. at 4-5. However, the explanation for this theory was relatively thin.

A status conference was held on November 4, 2020. Some of the deficiencies with Dr. Younger's report were discussed. Mr. Bynum planned to obtain a supplemental report.

The supplemental report from Dr. Younger was filed on December 14, 2020 as Exhibit 39. Dr. Younger opined that before the vaccination, Mr. Bynum was suffering from an incomplete or undeveloped *forme fruste* Sjögren's syndrome. Dr. Younger further opined that the "immune challenge initiated by the vaccine brought forth and resulted in a more complete manifestation of his underlying *forme fruste* primary SS and vasculitic peripheral neuropathy." Exhibit 39 at 4. Dr. Younger stated that evidence of the development of SS was apparent within approximately 48 hours of the vaccination. Id. at 6. Consistent with his previous report, Dr. Younger referenced polyclonal B-cell activation and cited an article by Brauner. Id.

This second report adequately complied with the expert instructions. Thus, the Secretary was directed to respond. As noted above, the Secretary presented reports from Dr. Callaghan and Dr. Mecoli, who addressed different aspects of Dr. Younger's reports.

Dr. Callaghan focused on Dr. Younger's opinion that Mr. Bynum suffered from lumbosacral radiculoplexus neuropathy. In Dr. Callaghan's view, "there is no evidence of this based on the medical record." Exhibit A at 5. If Mr. Bynum did suffer from lumbosacral radiculoplexus neuropathy, "diabetes would be the likely cause." Id. at 6. Dr. Callaghan also disagreed with Dr. Younger's opinion regarding onset. To Dr. Callaghan, Mr. Bynum had many symptoms for years before the vaccination. Id. Finally, with respect to causation, Dr. Callaghan quoted the Hadden article, which stated: "no causal relationship between immunisation and systemic or nonsystemic vasculitic neuropathy has been established." Id., quoting Exhibit 31 at 1568.[12]

Dr. Mecoli addressed the other aspect to Dr. Younger's opinion, that the pneumococcal vaccine contributed to Mr. Bynum's developing Sjögren's syndrome. Dr. Mecoli stated that from "the available data, the diagnosis of

[12] Dr. Callaghan identified the Hadden article as reference 3 and the Secretary filed the Hadden article as Exhibit A, tab 3. For the sake of consistency, this decision cites the Hadden article as Exhibit 31.

Sjogren's syndrome (either pre- or post-Prevnar vaccination), is questionable." Exhibit C at 5. Dr. Mecoli elaborated: "There is no positive lip biopsy, no objective evidence of dry eye, and no objective evidence of salivary gland involvement. In the present case, not only does the diagnosis of Sjogren's appear to be based on non-specific symptoms - myalgia, fatigue, cough, weakness, weight loss (Ex 39 [Dr. Younger's report] p6), but these symptoms existed prior to the Prevnar vaccination." Id. at 6. Nonetheless, Dr. Mecoli recognized that Mr. Bynum "does appear to have new and/or worsening symptoms post-Prevnar vaccine." Id. at 8. In addition, Dr. Mecoli disputed the opinion that the pneumococcal vaccine can cause Sjögren's syndrome. Id. at 8-9.

Mr. Bynum's response to these reports from two experts was to present reports from three people. First, Mr. Bynum filed another report from Dr. Younger. He generally defended the opinions that he previously expressed. Exhibit 51. Next, Mr. Bynum submitted a letter from Dr. Reams, who recounted his treatment of Mr. Bynum over the years and opined that any condition from before the vaccination (such as diabetes) did not cause the symptoms after the vaccination. Exhibit 56. Finally, Mr. Bynum filed a report from Dr. Dobbins. Dr. Dobbins declared: "There is much data to support Dr. Younger's proposition that Mr. Bynum's symptoms are a result of hyperreactivity of B Cells initiated by the PCV13 vaccine." Exhibit 57 at 3.

The Secretary obtained a report from Dr. Callaghan and Dr. Mecoli. Dr. Callaghan generally defended his opinions, including his challenge to the proposition that Mr. Bynum suffered from vasculitis or lumbrosacral radiculoplexus neuropathy. Exhibit E.

Dr. Mecoli, similarly, maintained his previously expressed opinions. His second report began: "In my initial report, I wrote that the diagnosis of Sjogren's syndrome was questionable. I will be more firm in this rebuttal report: The evidence the petitioner has Sjogren's syndrome is extremely weak." Exhibit F at 1. With respect to Dr. Dobbins's assertion that "There is much evidence to support Dr. Younger's proposition that Mr. Bynum's symptoms are a result of hyper-reactivity of B Cells initiated by the PCV13 vaccine," Dr. Mecoli responded "no such evidence is presented." Id. at 3.

The last report from a doctor was a second letter from Dr. Reams. Exhibit 75. Dr. Reams began his letter stating that he reviewed his chart for Mr. Bynum and the report from David Younger that Mr. Ragsdale had provided to him. Id. at 1. Dr. Reams wrote: "Mr. Bynum's symptoms and course of events post-vaccination do strongly suggest that he developed an autoimmune process as a

result of the Prevnar vaccine. Mr. Bynum's abrupt change was followed by a progressively deteriorating neurologic decline." Id. Dr. Reams also wrote: "Dr. Younger's opinion of autoimmune vasculopathy, PNS, and Sjogrens is supported by Mr. Bynum's symptomology and course."[13]

After the experts disclosed their opinions and the bases for their opinions, the next step was for the parties to argue their cases. Order, issued June 27, 2022. As part of this process, Mr. Bynum submitted updated medical records. Exhibits 76-77. He filed his brief and amended petition on November 1, 2022. The Secretary responded on January 6, 2023. Mr. Bynum replied on February 6, 2023.

As part of the briefing process, Mr. Bynum did "not request a hearing." Pet'r's Br. at 31. Mr. Bynum enjoyed multiple opportunities to present a persuasive case. After Dr. Younger's first report was found to be deficient, he was given a chance to improve it. Order, issued Nov. 5, 2020. Then, after the Secretary's experts critiqued the second report, Mr. Bynum had an opportunity to respond to their points. See Order, issued July 21, 2021. Likewise, Mr. Bynum had the last word in the briefs. See Pet'r's Reply, filed Feb. 6, 2023. Because both parties have had a fair opportunity to present their evidence and their arguments, an adjudication based upon the papers is appropriate. See Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018).

V. Standards for Adjudication

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357

[13] In this context, "PNS" probably refers to peripheral nervous system.

(Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

One element of a petitioner's case is to establish with preponderant evidence that the vaccinee suffers from the condition that a vaccine allegedly caused. Broekelschen v. Sec'y of Health and Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). When a petitioner does not satisfactorily establish a relevant diagnosis, special masters are not required to address whether the vaccine caused the injury. Lombardi v. Sec'y of Health & Hum. Servs., 656 F.3d 1343, 1353 (Fed. Cir. 2011). In considering whether a vaccinee suffers from a particular condition, a special master should consider all evidence. Within the field of the entire record, the opinions of treating doctors often stand out. Lombardi, 656 F.3d at 1353-54 (ruling that a special master was not arbitrary in rejecting a neurologic diagnosis offered by an expert retained in the litigation that a treating neurologist did not find); D'Angiolini v. Sec'y of Health & Hum. Servs., No. 99-578V, 2014 WL 1678145, at *24 (Fed. Cl. Spec. Mstr. Mar. 27, 2014) (indicating that the views of a treating doctor on diagnosis are "almost definitive"), mot. for rev. denied, 122 Fed. Cl. 86 (2015), aff'd without op., 645 F. App'x 1002 (Fed. Cir. 2016).

VI. Analysis

Mr. Bynum alleges the pneumococcal vaccine contributed to his developing two different conditions, Sjögren's syndrome and lumbrosacral radiculoplexus neuropathy. Am. Pet., filed Nov. 1, 2022, ¶¶ 14-15. The separate evaluations follow.

A. Sjögren's syndrome

Although Dr. Younger asserted that Mr. Bynum developed Sjögren's syndrome, Mr. Bynum did not substantiate that opinion persuasively. Two potential sources of information include treatment reports and opinions expressed during litigation.

1. Treatment Reports

A treating doctor has not diagnosed Mr. Bynum as suffering from Sjögren's syndrome. For example, Dr. Mecoli noted that Mr. Bynum's rheumatologist, Dr. Kenawy, did not mention "the possibility of Sjogren's syndrome, either associated with an inflammatory arthritis or as a separate, distinct entity." Exhibit C at 7. Although Dr. Younger responded to Dr. Mecoli's report, Dr. Younger did not identify any treating doctor who agreed with his opinion that Mr. Bynum suffered

from Sjögren's syndrome. See Exhibit 51 at 3-4. Similarly, the Secretary noted the lack of diagnosis from treating doctors, except for Dr. Reams (see Resp't's Br. at 25-26), yet Mr. Bynum does not contradict this assertion. See Pet'r's Reply at 2-10.

Throughout the years that Dr. Reams saw Mr. Bynum, Dr. Reams proposed a variety of diagnoses, including some that are not controversial like diabetes. Across this span of records, Dr. Reams did not suggest that Mr. Bynum suffered from Sjögren's syndrome.

Despite this lack of diagnosis, Dr. Reams endorsed Dr. Younger's proposed diagnosis of Sjögren's syndrome in a letter to Mr. Bynum's attorney. Dr. Reams wrote: "Although I am not a neurologist or a rheumatologist, I have treated hundreds of patients with possible or suspected autoimmune disorders. . . . Dr. Younger's opinion of . . . [Sjögren's] is supported by Mr. Bynum's symptomology and course." Exhibit 75.

Multiple factors reduce the persuasive value of Dr. Reams's February 7, 2022 letter. First, Dr. Reams did not propose that Mr. Bynum suffered from Sjögren's syndrome in any treatment record. Dr. Reams has not explained the inconsistency between how he treated Mr. Bynum and what he is saying in litigation. See Lombardi, 656 F.3d at 1355 (ruling that a special master was not arbitrary in declining to credit a conclusory letter from a treating physician that did not explain the basis for a diagnosis); Townsend v. Sec'y of Health & Hum. Servs., No. 14-266, 2024 WL 1081358 (Fed. Cl. 2024) (ruling that a special master was not arbitrary in declining to credit a letter from a treater that did not explain foundation for causation analysis); Ruiz v. Sec'y of Health & Hum. Servs., No. 02-156V, 2007 WL 5161754, at *14 (Fed. Cl. 2007) (ruling that a special master was not arbitrary in declining to credit a treating doctor's letter that was written five years later and did not match the treatment records); Frette v. Sec'y of Health & Hum. Servs., No. 14-1105V, 2017 WL 7421013, at *14 (Fed. Cl. Spec. Mstr. Dec. 29, 2017) (declining to credit a statement from treating doctor about events that allegedly happened two years and were not charted). Second, Dr. Reams supported Dr. Younger's opinion without the benefit of reviewing the opinion from Dr. Mecoli. Mr. Ragsdale's providing reports from only one of the two experts who opined on the Sjögren's syndrome diagnosis means that Dr. Reams has incomplete information. Third, Dr. Reams admits that he is not a rheumatologist. Thus, his ability to diagnose a rheumatological disorder seems at least unclear. At the end of the day, Dr. Reams's February 7, 2022 letter does not add much to the case. He essentially is deferring to Dr. Younger's opinion on diagnosis without explaining why Dr. Younger is persuasive.

Accordingly, the statements of treating doctors do not persuasively establish that Mr. Bynum suffered from Sjögren's syndrome. If anything, this type of evidence tends to show that Mr. Bynum did not have Sjögren's syndrome. Thus, for Mr. Bynum to carry his burden regarding diagnosis, he needs to rely upon opinions from the doctor he retained in the litigation.

2. Opinions from People Retained in the Litigation

Mr. Bynum advances the Dr. Younger's opinion as a basis for finding that he suffered from Sjögren's syndrome. Pet'r's Br. at 19. However, Dr. Younger is not persuasive.

Preliminarily, Dr. Younger's opinion on diagnosis changed without explanation. In Dr. Younger's first report, he was asked to describe the condition caused by the pneumococcal vaccination. Exhibit 30 at 3 (question 9); see also Instructions, issued Nov. 22, 2019. Dr. Younger answered: "Mr. Bynum developed autoimmune lumbosacral radiculoplexus neuropathy due to microscopic vasculitis as a response to PCV13 vaccination." Exhibit 30 at 4. Dr. Younger did not mention Sjögren's syndrome in this first report. Dr. Younger was called upon to develop his opinions. Order, issued Nov. 5, 2020.

In the second report, Dr. Younger added a diagnosis of Sjögren's syndrome. He wrote: "Mr. Bynum probably had pre-existing *forme fruste* primary Sjögren's syndrome." Exhibit 39 at 4. Dr. Younger did not explain that he came to recognize that Mr. Bynum suffered from Sjögren's syndrome in his December 14, 2020 report when he did not present the same opinion in his October 22, 2020 report. An explanation from Dr. Younger about this addition to his diagnosis might have enhanced the persuasiveness of Dr. Younger's opinion.

More importantly, even when Dr. Younger was disclosing an opinion that Mr. Bynum suffered from Sjögren's syndrome, Dr. Younger's presentation was vague. The November 22, 2019 Instructions direct experts to describe the "diagnostic criteria" for any relevant condition. ¶ 4.b. Yet, Dr. Younger's second report does not include any diagnostic criteria for Sjögren's syndrome. See Exhibit 39; see also Resp't's Br. at 23. Without this disclosure about the criteria relevant to Dr. Younger, finding Dr. Younger's opinion on diagnosis to be reliable is challenging. See Orloski v. Sec'y of Health & Hum. Servs., 147 Fed. Cl. 713, 725 (2020) (ruling that special master was not arbitrary in not crediting the statement of a treating doctor who did not provide diagnostic criteria), aff'd in non-precedential op., 839 F. App'x 538 (Fed. Cir. 2021).

Dr. Younger relied upon the following symptoms and signs: fever, myalgia, extreme fatigue, cough, weakness, dysphagia, and the development of a neuropathy. Exhibit 39 at 5; Exhibit 51 at 3; see also Pet'r's Br. at 30. Dr. Younger emphasizes that approximately 20 percent of Sjögren's syndrome cases begin with neurologic problems with the reports of dry eyes / dry mouth following. Exhibit 39 at 4-5. Dr. Younger does not point to the positive SS-A antibody test as supporting the diagnosis of Sjögren's syndrome.

Dr. Mecoli convincingly showed that Dr. Younger's opinion regarding diagnosis is mistaken.[14] Problems like myalgia, fatigue, cough, weakness, and weight loss are "non-specific." Exhibit C at 6.

> Non-specific signs and symptoms such as fatigue, fever, dysphagia, and cough cannot be used as justification for a diagnosis of Sjogren's. They can be 'supportive of' or 'consistent with', but they, by themselves or even in combination, do not serve as the foundation for the diagnosis. They simply do not have enough specificity.

Exhibit F at 2. As to the criteria that are recognized as useful in identifying people with Sjögren's syndrome, Dr. Mecoli accurately stated: "There is no positive lip biopsy, no objective evidence of dry eye, and no objective evidence of salivary gland involvement." Exhibit C at 6. Dr. Mecoli also addressed why the slightly positive SS-A antibody test was not diagnostic. Id.

Dr. Mecoli also responded to Dr. Younger's point that not everyone with Sjögren's syndrome will have dryness on their initial evaluation, agreeing with Dr. Younger. But, Dr. Mecoli demonstrated the limited value of this point. "[W]e have the benefit of 5+ years of treatment records since the patient received the Prevnar vaccination. During this time span, the patient has not endorsed any sicca or has not undergone any testing for Sjogren's syndrome to my knowledge." Exhibit C. At best, Mr. Bynum identified one medical record from 2017 in which Mr. Bynum reported dry mouth and difficulty swallowing. Pet'r's Reply at 6, citing Exhibit 11 at 11 (Aug. 23, 2017). However, this report appears isolated and, in some places, Mr. Bynum denied dry mouth. Exhibit 11 at 5 (Sept. 20, 2017); Exhibit 14 at 10 (Oct. 20, 2017), 6 (Nov. 20, 2017).

[14] "Convincingly" is used to connote the disparity in the quality of opinions from Dr. Younger and Dr. Mecoli. In short, Dr. Younger's opinion regarding diagnosis was poor and Dr. Mecoli's opinion regarding diagnosis was strong.

3. Disposition

The evidence regarding diagnosis falls far short of showing that Mr. Bynum suffered from a disease that has, according to his retained expert, eluded detection by multiple doctors who have treated him for multiple years. There is not preponderant support for finding that he suffered from Sjögren's syndrome at any time. Mr. Bynum is not entitled to compensation on any theory that the pneumococcal vaccine caused him to develop Sjögren's syndrome or caused any pre-existing Sjögren's syndrome to worsen.

A finding that Mr. Bynum did not have Sjögren's syndrome renders the question of whether the pneumococcal vaccine caused him to suffer Sjögren's syndrome hypothetical. There is no reason to explore the more complicated topic of whether a pneumococcal vaccine can engender the production of B cells that would lead to Sjögren's syndrome.

B. Vasculitic Peripheral Neuropathy / Lumbrosacral Radiculoplexus Neuropathy

1. Development of Opinions and Arguments regarding a Neurologic Problem Possibly Affecting Mr. Bynum

The parties' and their experts' development of whether Mr. Bynum suffered from vasculitic neuropathy and/or lumbosacral radiculoplexus neuropathy was generally poor. This weakness in presentation hinders Mr. Bynum's case because he bears the burden of proof.

The trouble started with Dr. Younger's first report. Although the November 22, 2019 Instructions directed experts to provided diagnostic criteria, Dr. Younger stated that "Mr. Bynum developed autoimmune lumbrosacral radiculoplexus due to microscopic vasculitis as a response to PCV13 vaccination," Exhibit 30 at 4, without identifying any diagnostic criteria. Dr. Younger, thus, was instructed to supplement his report. Order, issued Nov. 4, 2020. Dr. Younger supplemented his opinion by citing an article by Dyck, which was filed as Exhibit 48.[15] The Dyck article, as discussed below, is unquestionably about lumbosacral radiculoplexus neuropathy. Thus, this reference relates to Dr. Younger's assertion that "the manifestation and clinical history of Mr. Bynum's severe radiculoneuropathy, its axonal features, clinical confirmation of peripheral neuropathy, the pre-exisiting

[15] P.J. Dyck et al., "Non-diabetic lumbosacral radiculoplexus neuropathy: natural history, outcome and comparison with diabetic variety," 124 Brain 1197 (2001), filed as Exhibit 48.

forme fruste of Sjögren's Syndrome are consistent with MV [microvasculitis] and associated LRPN." Exhibit 39 at 5. These reports disclosed that Dr. Younger's opinion was that Mr. Bynum suffered from lumbosacral radiculoplexus neuropathy.

Dr. Callaghan, in turn, challenged the assertion that lumbosacral radiculoplexus neuropathy was affecting Mr. Bynum. Relying upon the same Dyck article, Dr. Callaghan stated that lumbosacral radiculoplexus neuropathy "is characterized by severe pain followed by weakness that starts unilaterally in one leg." Exhibit A at 5. In Dr. Callaghan's opinion, Mr. Bynum did not display this symptom. Id. at 5-6. Dr. Callaghan did not opine as to whether Mr. Bynum suffered vasculitic neuropathy.

In response, Dr. Younger did not clarify his opinion. He stated that due to the presence of a "more severe and additional symptomology," "the neurologic aspects of Mr. Bynum's condition cannot be reduced to a single neurologic condition." Exhibit 51 at 1. Nevertheless, and without referring to the Dyck article, Dr. Younger seemed to maintain his opinion that Mr. Bynum suffered from lumbosacral radiculoplexus neuropathy. Id. at 1-2.

Dr. Callaghan largely restates his prior opinions. See Exhibit E at 1. This report completed the disclosure of opinions from people retained for this litigation.

As part of the briefing process, Mr. Bynum amended his petition. Although it had appeared that Dr. Younger was advancing lumbosacral radiculoplexus neuropathy, Mr. Bynum alleged that the "Prevnar vaccine . . . caused him to develop vasculitis and vasculitic peripheral neuropathy." Am. Pet. ¶ 14. The amended petition does not use the term "lumbosacral radiculoplexus neuropathy." Mr. Bynum's initial brief focused on vasculitis peripheral neuropathy. Pet'r's Br. at 4-7, 22, and 28. This focus, however, did not prevent Mr. Bynum from at least mentioning "lumbosacral radiculoplexus neuropathy." Id. at 6.

The Secretary at least attempted to address both vasculitic peripheral neuropathy and lumbosacral radiculoplexus neuropathy. In the Secretary's view, Mr. Bynum did not establish that he suffered from either condition. Resp't's Br. at 42-47.

Mr. Bynum's final word was more attentive to the question of whether he suffered from Sjögren's syndrome. There is, however, some mention of whether vasculitic peripheral neuropathy and lumbosacral radiculoplexus neuropathy could be diagnoses for Mr. Bynum. See Pet'r's Reply at 18-19. This relatively short

discussion did not explicitly cite either the Hadden diagnostic criteria for vasculitic peripheral neuropathy or the Dyck diagnostic criteria for lumbosacral radiculoplexus neuropathy.

Based upon this record of evidence and argument, the undersigned must "first determine which injury was best supported by the evidence in the record before applying the Althen test." Broekelschen v. Sec'y of Health and Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). To do so, the evidence is organized as to whether it came from a doctor who treated Mr. Bynum or came as an opinion from a person retained in the context of the litigation.

2. Treatment Reports

A treating doctor has not diagnosed Mr. Bynum as suffering from "vasculitic peripheral neuropathy" or "lumbosacral radiculoplexus neuropathy." This lack of diagnosis is evident from a close review of Dr. Barrio, the neurologist who would most naturally diagnose a neurologic problem, and Dr. Reams, the general physician who most frequently saw and examined Mr. Bynum until before and after the vaccination. Each saw Mr. Bynum in 2015 and later in 2017. The following is a discussion of the records generated in 2015 and 2017.

a) Records Created in 2015

Mr. Bynum received the pneumococcal vaccine on June 26, 2015. Exhibit 1 at 3. Thus, the focus of analysis is on medical records created within a few months of the vaccination.

In Mr. Bynum's presentation to Dr. Brian Shaheen on June 30, 2015, he complained about dizziness, unstability, and headaches. Exhibit 5 at 58. Dr. Shaheen did not diagnose Mr. Bynum as suffering from "vasculitic peripheral neuropathy" or "lumbosacral radiculoplexus neuropathy." Id. Dr. Younger did not cite this report as suggesting that Mr. Bynum suffered from either of these conditions. See Exhibit 39 at 5.

A more critical report was Dr. Barrio's August 31, 2015 report. Mr. Bynum has cited this report as evidencing his claim that he suffered from vasculitic peripheral neuropathy or lumbosacral radiculoplexus neuropathy. See Pet'r's Br. at 6. On that day, Mr. Bynum told Dr. Barrio that after the Prevnar vaccination, "he started developing significant issues with dizziness, headache, slight altered mental status, dysphagia, tremor with difficulty with coordination that have all been slightly progressive." Exhibit 7 at 23. For these problems, Dr. Barrio "recommended an MRI of his brain to rule out any other postviral

encephalomyelitis versus autoimmune encephalitis cause." Id. at 25. Mr. Bynum draws attention to Dr. Barrio's suggestion that Mr. Bynum might have an "autoimmune" problem. Pet'r's Br. at 6. However, Mr. Bynum overlooks the context that Dr. Barrio was concerned in the context of a disorder of the central nervous system, which is why Dr. Barrio ordered an MRI of the brain. Exhibit 7 at 23.

When Dr. Barrio reviewed Mr. Bynum's neurologic system, Dr. Barrio recorded that Mr. Bynum reported "numbness, tingling, lightheadedness, vertigo, morning headaches, focal weakness and unsteady gait." Id. at 24. Mr. Bynum also cites these symptoms. Pet'r's Br. at 24. However, Mr. Bynum does not cross-reference either the Hadden diagnostic criteria for vasculitic peripheral neuropathy or the Dyck diagnostic for lumbosacral radiculoplexus neuropathy. In any event, Dr. Barrio's plan to address these symptoms was to order an EMG / NCS. Exhibit 7 at 26.

The October 15, 2015 lower extremity EMG / NCS could have been discussed in more detail. Dr. Barrio included the results of specific tests. Exhibit 7 at 11-14. His bottom-line impression was that the "electrodiagnostic study also reveals evidence of moderate chronic multilevel lumbosacral radiculopathy on the right and left." Id. at 10.

In the follow-up appointment on October 23, 2015, Dr. Barrio did not diagnose Mr. Bynum with vasculitic peripheral neuropathy or lumbosacral radiculoplexus neuropathy. See Exhibit 7 at 5 (Oct. 23, 2015). Dr. Barrio also did not order any treatment for these conditions. Id.

The parties do not discuss any diagnoses made (or not made) by Dr. Barrio in 2015. Mr. Bynum refers to a November 9, 2015 report from Dr. Reams. Pet'r's Br. at 5. Then, Mr. Bynum informed Dr. Reams that he was having pain in his legs bilaterally. He stated the pain is "burning" and is associated with "limping, . . . tingling in the legs and confusion." Exhibit 5 at 86. Dr. Reams ordered an MRI of Mr. Bynum's lumbar spine. Id. at 88. Dr. Reams did not diagnose Mr. Bynum as suffering from vasculitic peripheral neuropathy or lumbosacral radiculoplexus neuropathy.[16]

[16] In early 2016, a home health aide memorialized that Mr. Bynum was having difficulty walking. Exhibit 12 at 5; see also Pet'r's Br. at 5. However, difficulty in walking is not diagnostic for either vasculitic peripheral neuropathy or lumbosacral radiculoplexus neuropathy.

b) Records Created in 2017

Medical records that Dr. Barrio created in 2017 are featured more prominently in Mr. Bynum's argument that he suffered from vasculitic peripheral neuropathy or lumbosacral radiculoplexus neuropathy. See Pet'r's Br. at 4; see also Pet'r's Reply at 18. In Mr. Byum's view, Dr. Barrio diagnosed him with "peripheral neuropathy" and "vasculitis." But, Mr. Bynum appears to be taking these comments out of context.

Mr. Bynum renewed treatment with Dr. Barrio on August 23, 2017. Exhibit 11 at 10. Dr. Barrio wrote that Mr. Bynum said his symptoms, such as tremor, memory loss, gait instability, have progressed over the past two years. Id. In this context, Dr. Barrio's impression included eight items, of which two were "vasculitis" and "neuropathy." Id. at 12. Dr. Barrio, again, ordered studies of Mr. Bynum's brain. After these studies were done, Dr. Barrio ordered another EMG / NCS. Id. at 6 (Sep. 20, 2017).

The EMG / NCS took place on October 3, 2017. Exhibit 14 at 15. This combined study "did show a severe length-dependent peripheral neuropathy that appears to have more axonal greater than demyelinating features." Id. The follow up was with Mr. Johnson and then with Dr. Barrio. Neither diagnosed Mr. Bynum with "vasculitic peripheral neuropathy" or "lumbosacral radiculoplexus neuropathy." See Exhibit 14, passim.

Years later, in a letter for Mr. Ragsdale, Dr. Reams supported "Dr. Younger's opinion of autoimmune vasculopathy." Exhibit 75 at 2. But, the same flaws reduce the persuasive value of this opinion. Dr. Reams is not a neurologist; he did not review the opinion from the expert the Secretary retained, and he did not explain why he did not diagnose Mr. Bynum with an "autoimmune vasculopathy" during his treatment.

In short, taken individually or collectively, the reports created during treatment do not support a finding that Mr. Bynum suffered from either vasculitic peripheral neuropathy or lumbosacral radiculoplexus neuropathy.

3. Opinions from People Retained in the Litigation

Mr. Bynum argues that Dr. Younger's opinion supports his claim regarding vasculitic peripheral neuropathy. Pet'r's Br. at 4. However, Dr. Younger's opinion is not persuasive.

As discussed above, it is not entirely clear that Dr. Younger opined that Mr. Bynum suffered from vasculitic peripheral neuropathy. The thrust of Dr. Younger's reports was that Mr. Bynum suffered from lumbosacral radiculoplexus neuropathy. See Exhibit 30, Exhibit 39. Dr. Younger, for example, did not cite the Hadden article for the diagnostic criteria of vasculitic peripheral neuropathy.

To the extent that Mr. Bynum is attempting to springboard the Hadden diagnostic criteria as a basis for finding that Mr. Bynum suffered from vasculitic peripheral neuropathy, that leap is too far for Mr. Ragsdale to make. See Pet'r's Br. at 4-5. One factor potentially contributing to a "suggestive" diagnosis of vasculitic neuropathy is "electrodiagnostic evidence of an axonal neuropathy (symmetric or asymmetric)." Exhibit 31 (Hadden) at 1572 (table 4, item I.a.). It might have been helpful for Dr. Younger to address whether the October 15, 2015 lower extremity EMG / NCS supported his opinion. Without an expert's interpretation of the EMG / NCS, the undersigned is reluctant to find that the EMG / NCS conducted approximately four months after vaccination supports a diagnosis of vasculitic peripheral neuropathy.

Dr. Callaghan directly states that the October 15, 2015 EMG / NCS "did not reveal[] a lumbosacral radiculoplexus neuropathy nor the characteristic asymmetry that would be seen in this condition." Exhibit A at 6. Saying the EMG / NCS is not consistent with "a lumbosacral radiculoplexus neuropathy" is not exactly the same as saying the EMG / NCS is inconsistent with a vasculitic peripheral neuropathy.[17] In any event, Dr. Younger did not contest how Dr. Callaghan interpreted the October 15, 2015 EMG / NCS. For example, Dr. Younger did not say that the October 15, 2015 EMG / NCS supported a diagnosis of either vasculitic peripheral neuropathy or lumbosacral radiculoplexus neuropathy. See Exhibit 51.

Instead, Dr. Younger maintained that Mr. Bynum's reports of weakness satisfied the diagnostic criteria for lumbosacral radiculoplexus neuropathy set forth in Dyck. Id. at 1. But, Dr. Younger has missed the point. Dr. Callaghan had opined that lumbosacral radiculoplexus neuropathy includes "weakness that starts unilaterally in one leg." Exhibit A at 5. The Dyck article supports this definition

[17] To some degree, Dr. Callaghan's evaluation of whether Mr. Bynum suffered from lumbosacral radiculoplexus neuropathy is understandable. The report to which Dr. Callaghan is responding did not claim that Mr. Bynum suffered from vasculitic peripheral neuropathy.

as all 57 patients had "asymmetric lower limb pain." Exhibit 48 at 1199. Mr. Bynum's leg pain and weakness was bilateral. Exhibit 5 at 86 (Nov. 9, 2015).

Furthermore, at least to a degree, Dr. Younger's opinion that Mr. Bynum suffered from some type of peripheral neurologic disorder depends upon Mr. Bynum suffering from Sjögren's syndrome. See Pet'r's Reply at 8-9; Exhibit 39 at 5 (Dr. Younger: "In my opinion, Mr. Bynum's neurologic manifestations are probably a result of vaccination related autoimmune vasculopathy overlapping, or in association with, contemporaneous SS."). For the reasons explained in section VI.A., this predicate assumption is not justified with preponderant evidence.

4. Disposition

When considered as a whole, the record does not support a finding that Mr. Bynum suffered from either vasculitic peripheral neuropathy or lumbosacral radiculoplexus neuropathy. The doctors who treated Mr. Bynum across several years did not use those terms and did not prescribe any treatments for those conditions. Moreover, the reports from Dr. Younger were confusing and lacked a persuasive explanation for how Mr. Bynum met a relevant set of diagnostic criteria. Accordingly, there is no need to consider whether the pneumococcal vaccine can cause either vasculitic peripheral neuropathy or lumbosacral radiculoplexus neuropathy.

VII. Conclusion

Long before Mr. Bynum initiated this litigation, he stated that the pneumococcal vaccine might have caused his problems. Thus, Mr. Bynum's good faith belief about suffering an injury due to the vaccination is not questioned. But, Mr. Bynum must rest his case on more than just his belief. The evidence shows that Mr. Bynum did not establish that he suffered from any of the conditions that he associates with the vaccination. Therefore, he cannot receive compensation.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master